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| APPLICATION NO. | FILING | DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|------------|------|----------------------|------------------------|------------------|
| 09/283,431 | 04/01/1999 | | WEN-QIANG ZHOU | 475.08.423 | 9988 |
| 7590 08/08/2006 | | | EXAMINER | | |
| WAYNE A K HALE & DOR | | | VIVLEMORE, TRACY ANN | | |
| 60 STATE ST | | | ART UNIT | PAPER NUMBER | |
| BOSTON, MA 02109 | | | | 1635 | |
| | | | | DATE MAILED: 08/08/200 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------------|--|--|--|--|--|
| Office Action Summary | | 09/283,431 | ZHOU ET AL. | | | | | |
| | | Examiner | Art Unit | | | | | |
| | | Tracy Vivlemore | 1635 | | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status | | | | | | | | |
| 1) 又 | Responsive to communication(s) filed on 30 Ma | av 2006. | | | | | | |
| - | This action is FINAL . 2b) ☐ This action is non-final. | | | | | | | |
| / | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| / | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>4-25</u> is/are pending in the application. | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | | |
| 6)🖂 | Claim(s) <u>4-25</u> is/are rejected. | | | | | | | |
| 7) | | | | | | | | |
| 8)[| Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Applicati | ion Papers | | | | | | | |
| 9) | The specification is objected to by the Examine | r. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| Priority ι | under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| Attachmen | • • | o□ | (DTO 442) | | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail Da | | | | | | |
| 3) 🔲 Infori | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | | atent Application (PTO-152) | | | | | |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to arguments: Priority

The priority date for the claimed invention is the filing date of the instant application, April 1, 1999. No support could be found in provisional application 60/080321 for the claimed embodiment of deoxyribonucleotide POPS blocks.

Applicant asserts in the remarks filed May 30, 2006 that support exists throughout the provisional application for the claimed invention. Applicant points to paragraphs 4-10, figures 2-5 and table 1. This argument is not persuasive because the claimed invention is directed to oligonucleotides having deoxynucleotide POPS blocks, which are regions of deoxynucleotides having alternating phosphodiester and phosphorothioate linkages. The portions of the provisional application pointed to by applicant are summarized by table 1, which shows the oligonucleotides studied. While these oligonucleotides do contain regions of POPS blocks, these appear only in conjunction with 2'-O-substituted nucleotides, not deoxynucleotides. All the oligonucleotides disclosed in the provisional application have deoxynucleotides linked solely by phosphorothioates. Therefore, the priority date of the claimed invention remains April 1, 1999.

Double Patenting

Claims 4-25 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-8 of copending Application No. 10/291,058.

Applicant has previously noted that a provisional obviousness-type double patenting rejection will be withdrawn when it is the only remaining rejection. However, until this should happen it is proper that the provisional obviousness-type double patenting rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 4-14 remain rejected under 35 U.S.C. 102(e) as being anticipated by Manoharan for the reasons set forth in the office action mailed February 8, 2006.

Applicant argues that the disclosure of Manoharan teaches oligonucleotides wherein the regions of 2' modified nucleosides are connected by alternating phosphodiester and phosphorothioate linkages, not the intervening deoxynucleotides. Applicant asserts that the sequence pointed out by the examiner supports this disclosure, stating that SEQ ID NO: 2 has phosphorothioate linked deoxynucleotides. These arguments are not persuasive because the disclosure of Manoharan is not limited to the embodiment recited in the first sentence of the detailed description of the preferred embodiments. Column 6 discloses the structure of the oligonucleotide as recited in claim 7, which comprise alternating phosphodiester and phosphorothioate linkages in a 1:1 ratio wherein the 2' sugar position can be deoxy, fluoro or O-alkyl, -

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alkenyl or -alkynyl. Contrary to applicant's arguments, SEQ ID NO: 2 does not have phosphorothioate linked deoxynucleotides. The sequence listing, shown at column 27, shows that this sequence has alternating phosphodiester and phosphorothioate linkages.

Claim Rejections - 35 USC § 103

Claims 15-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Manoharan for the reasons set forth in the office action mailed February 8, 2006.

Applicant traverses the 103 rejection over Manoharan by stating that regardless of the configuration, Manoharan does not teach oligonucleotides wherein the deoxynucleotides are linked by alternating phosphorothioate and phosphodiester linkages. The arguments regarding Manoharan's teachings have been addressed in the response to arguments above.

Applicant further directs the examiner to a teaching of Manoharan that oligonucleotides with alternating linkages throughout do not function by an RNase H mechanism while the oligonucleotides of instant claims 15-25 do act through RNase H. These arguments are not persuasive because the portion of Manoharan cited by applicant actually begins with the phrase, "it is believed". Therefore, this sentence is not a teaching, but a conjecture as to mechanism. With regard to applicant's assertion that the oligonucleotides of claims 15-25 act through RNase H, this argument is not because the instant claims contain only structural limitations and no such mechanism of action is recited.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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Tracy Vivlemore Examiner Art Unit 1635

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JANE ZARA, PH. DER